

REMARKS

This preliminary amendment is responsive to the Final Office Action dated October 12, 2010. Applicant respectfully requests reconsideration of the rejections in view of the remarks below. In the application claims 29 - 34 are pending and each claim stands rejected under Adams et al., U.S. Patent Publication No. 2003/0132267 ("Adams"), alone or in combination with Deem, U.S. Patent No. 6,558,400.

Claim 29

Claim 29 is directed to a gastroplasty device that includes first and second tissue acquisition members, each acquisition member including a tissue receiving cavity, and a stapler. Claim 29 now includes the feature whereby a vacuum source is located at an opposite end of an opening of the cavity.

In order to assess the rejection for obviousness, one must look at the prior art for what it teaches and what it does not. The Adams reference discloses a self-described resectioning device as evidenced by its title. It is designed for excising tissue and approximating the surrounding tissue to close the void created by the excision. [Adams, ¶0003]. Adams includes a cutting blade immediately adjacent a stapler so that the tissue can be cut and stapled together at the same time. Because of the nature of the Adams' device, there is a goal to cut as little tissue as possible while still excising the lesion or other malignancy. Further, while not explicitly disclosed, the Adams resectioning device grasps only a single fold of tissue.

Conversely, the present invention has the objective of acquiring two folds of tissue to reduce the volume of a hollow body organ such as a stomach. The present invention's configuration "creat[es] a tissue structure that reflects the geometry of the mold." [¶00056 of Specification]. The Applicant's disclosure talks about how "because of the manner in which the tissue is acquired, the tissue intimately surrounds the cartridge

member and anvil member to define or calibrate the subsequent volume of the resulting gastric lumen." *Id.*

Turning to Claim 29 as amended, the vacuum source is disposed opposite the opening of the cavity. The tissue configuration of, for example, FIGS. 5C and 5H of the Applicant's disclosure could not be readily achieved without this feature, and could not be achieved in any manner by the Adams device. This is because Adams' passing mention of the use of suction at paragraph 100, cited by the Office Action, confirms only the need to draw a single fold of tissue into the cutting mechanism, not shape the surrounding tissue structure by drawing two folds of tissue into the acquisition cavities. Even then, the only description of the use of suction in Adams is with the endoscope, which is not even part of either of the asserted tissue acquisition members relied upon by the Office Action.

The Office Action offers that "it would have been obvious to one of ordinary skill in the art to provide a vacuum port that is coupled to each receiving cavity in the embodiment of Figures 22 -25 in order to further 'draw a tissue section into the gap between the anvil member 10 and the proximal housing 12 and to prevent debris from accumulating between the two acquisition members with the help of a shield 31'." Applicant respectfully disagrees. The Adams' device of Figures 22-25 has only a single opening. As such, the Office Action fails to explain why more vacuum ports would draw tissue into the gap any better than one port, since the same vacuum force could be just as easily accomplished with a single port. That is, the same vacuum can be created in the Adams device's interior with one port as with two or more. Thus, the basis for the proposed modification does not withstand scrutiny. Further, there would be no impetus to modify the Adams resectioning device in such a manner so as to draw in two folds of tissue into the device.

Moreover, the proposed modifications suggested by the Office Action represent a radical departure from the embodiment disclosed, with no suggestion for why the extra

cost, complexity, and effort would be undertaken by one of ordinary skill in the art. The recently released Obviousness Guidelines published in the Federal Register, Volume 75, No. 169 dated Sept. 1, 2010 ("Examination Guidelines Update: Developments In The Obviousness Inquiry After KSR v. Teleflex"), addresses this issue:

"an argument for obviousness was an extra process step that added an additional component to a known, successful marketed formulation. The proposed modification thus amounted to extra work and greater expense for no apparent reason. This is not the same as combining known prior art element A and B when each would have been expected to contribute its own known properties to the final product." At Page 53647 (emphasis added)

The prior art relied upon by the Office Action does not teach using separate vacuum sources in each tissue acquisition cavity, and doing so would serve no purpose for Adams' device or further its objectives. This would merely add cost and complexity with no benefits, since the tissue will enter the Adams' device as a function of the vacuum created within, regardless of the number or location of the vacuum ports. The Federal Circuit has found that this type of rejection, where no real benefit is achieved, does not satisfy the requirements for obviousness, as set forth in the surrounding text of the quoted passage above in connection with In Re Omeprazole Patent Litigation, 536 F.3d 1361 (Fed. Cir. 2008).

Thus, Applicant respectfully submits that the rejection of Claim 29 as amended based on Adams cannot be sustained and is properly withdrawn.

Claim 31 as amended further includes the feature whereby the vacuum sources are independently actuable. This is discussed in the specification of the Applicant's application, and this feature allows two folds of tissue to be acquired without the need for a septum. [See, e.g., paragraph 00067]. There is no articulated clear purpose for modifying the Adams' device to employ dual, but separately operable (sequential), vacuum ports. Accordingly, Applicant respectfully submits that Claim 31 is independently allowable on this alternate basis.

The Remaining Claims

The remaining pending claims all share a feature discussed above which renders the claim patentably distinguishable over the cited art. Accordingly, Applicant respectfully submits that the application as constituted is now in condition for allowance and early notification of same is respectfully solicited. If the Examiner believes that a telephone conference will further the prosecution of this case, the Examiner is kindly invited to contact the undersigned at the number below.

The Commissioner is authorized to charge any deficiencies or fees in connection with this preliminary amendment to Deposit Account No. 06-2425.

Respectfully submitted,
FULWIDER PATTON LLP

By: /michael j. moffatt/
Michael J. Moffatt
Registration No. 39,304

MJM:spc
Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
428986.1